K122225

APR 2 6 2013

510(K) SUMMARY FOR STERILE RADIOLUCENT SKULL PINS

Manufacturer:	Brainlab AG Kapellenstrasse 12 85622 Feldkirchen Germany Phone: +49 89 99 15 68 0 Fax: +49 89 99 15 68 33
Submitter:	Rainer Birkenbach
Contact person:	Alexander Schwiersch
Summary date:	4/22/2013
Device:	Sterile Radiolucent Skull Pins
Trade name:	Sterile Radiolucent Skull Pins
Common/Classification Name:	Disposable Head Pins
Predicate Device:	Brainlab Headpins (K954789)
Device classification name:	Neurosurgical Head Holder (Skull Clamp)
Regulatory Class:	Class II
Regulation Number:	
Product Code:	HBL
Intended use:	Sterile Radiolucent Skull Pins are designed for the fixation of a compatible head-holder unit to the patient's skull. **This allows the fixation of the head and neck** during craniotomy and subsequent neurosurgical procedures. These pins reduce the incidence of artifacts in images acquired intra-operatively using CT, MR (Conditional) or fluoroscopy
Device description:	The Sterile Radiolucent Skull Pins are part of a fixation system which provides rigid immobilization of the patient's skull during surgery. The Pins are the components which get in direct contact with the patient and are made of Carbon-Fiber Reinforced PEEK. The Pins are designed to penetrate the skull tabula externa to provide rigid fixation to compatible head-holder units while significantly reducing imaging artifacts. **The Sterile Radiolucent Skull Pins are intended for use by physicians or their assistants in a hospital environment only.** The product may not be used repeatedly and is a single-use device accordingly. A compatible head-holder unit is required for the safe and effective use of the device. **The use scenario is primarily rigid fixation of the patient's skull during surgery e.g. percutaneous craniotomy.** The device requires the same user

actions as the listed predicate device, namely insertion and removal from the head-holder unit. A valid fixation setup with a compatible head-holder unit consists of exactly three sterile pins.

Substantial equivalence:

The Sterile Radiolucent Skull Pins have been verified and validated using both clinical and non-clinical data according to Brainlab procedures for product design and development. The information provided by Brainlab in this 510(k) application supports the claim of substantial equivalence with the predicate device Brainlab Headpins.

A clinical study involving 11 patients (male and female aged over 5 years old as per the selection criteria) undergoing craniotomy validated that the device is suitable for the intended use as part of a rigid fixation system for craniotomy and neurosurgical procedures supporting the claim of substantial equivalence with the predicate device.

Non-clinical data collected regarding mechanical performance testing, compatibility testing with specified compatible head-holder units and image artifact testing showed that the new device is capable of performing in an equivalent way to the predicate device but with improvements to the artifact performance for intra-operative imaging.

Changes to Predicate Device:

The changes compared with the predicate device are that the shaft of the pin has changed diameter and is smooth to press fit into the head clamp rather than screw into a head ring. The predicate device was made of two components (ceramic tip assembled into a PEEK threaded screw) whereas the new device is molded entirely of PEEK. Also the Brainlab Headpins came with a torque wrench to limit the forces while tightening but for the Sterile Radiolucent Skull Pins this is not included as it is built into or is an accessory of the head holder.

The predicate device is reusable and delivered non-sterile to be steam sterilized by the user before each use. The Sterile Radiolucent Skull Pins are single use and delivered sterile (sterilization method – EO).

Both the predicate and the Sterile Radiolucent Skull Pins are labeled as compatible with MR. The complete skull pins MR Conditional labeling can be seen in the user manual.

The sum of changes for this device does not significantly affect the safety or effectiveness of the device as the operating principle is identical, the essential shape has not changed and no new materials are being used (the ceramic material is excluded, the part is solely made of PEEK now instead of being two assembled components) so the device is substantially equivalent to the predicate device.

Verification/validation summary:

The verification activities consisted of testing the mechanical properties of the pin through a range of compression and shear tests, imaging comparison study and Magnetic Resonance (MR) compatibility testing. The following tests were performed for imaging and MR Compatibility:

Test Protocol	Standard	Summary
Measurement of Magnetically Induced Displacement Force on Medical Device in the MR environment	ASTM F2052-06e1	No magnetically induced displacement force was detectable for the given test conditions.
Measurement of Magnetically Induced Torque on Medical Devices in the MR Environment	ASTM F2213-06	Magnetically induced torque of 10μNm < worst case torque due to gravity of ≈1.077mNm
Measurement of Radio Frequency Induced Heating Near Passive Implants during MR Imaging – 1.5 Tesla	ASTM F2182-11a *	One single "Skull Pin" produced a temperature rise of less than 2.6°C (with a background temperature increase of ≈ 1.5°C) at a maximum whole body averaged specific absorption rate (SAR) of ≈ 2.3 W/kg assessed as per the standard.
Measurement of Radio Frequency Induced Heating Near Passive Implants during MR Imaging – 3 Tesla	ASTM F2182-11a *	One single "Skull Pin" produced a temperature rise of less than 5.9°C (with a background temperature increase of ≈ 2.8°C) at a maximum whole body averaged specific absorption rate (SAR) of ≈ 2.5 W/kg assessed as per the standard
Evaluation of MR Image Artifacts from passive Implants	ASTM F2119-07	Worst artifacts for spin echo sequence = 1.45mm / 1.47mm (orientation Skull Pin length/diameter). Worst artifacts for gradient echo sequence = 2.14mm / 1.94mm (orientation Skull Pin length/diameter)
CT Artifacts of Radiolucent Skull Pins	N/A, Comparative Test	Using a Siemens Sensation Open with parameters KV = 120 and ST = 1.0mm the following image artifacts (quantified by the Hounsfield Unit (HU)) were observed: • DORO® Disposable Skull Pins, Titanium >3070 HU • Integra MAYFIELD® Radiolucent Skull Pins > 3070 HU • Predicate Pins = 280 HU • Brainlab Radiolucent Skull Pins = 490 HU

All tests were passed according to the predetermined acceptance criteria stemming from the intended use.

* The ASTM F2182-11a standard (RF Heating for implants) was used for this test even though the product is not an implant as this enables a standardized RF Heating test set up to be used. A simulation was run which verified that complete immersion in gel creates more RF heating than the case where the test object is in air and only lightly touching a gel phantom (mirroring the clinical case), so is the worst case and can be used to determine the maximum RF heating .

The cleaning, sterilization and packaging validations, including accelerated aging and transportation testing, have been successfully completed to the pre-approved protocol.

Clinical tests being submitted include a series of mechanical tests on human cadavers which verified that the pins have the required performance and properties to meet the intended use. Also, Brainlab released an unsterile version of the pins (article name: "Disposable Radiolucent Skull Pins") in non-US markets to collect customer feedback regarding performance, side-effects and usability and the results have been collated as a Post-Market Clinical Study. Subjects tested were both female and male aged over 5 years old undergoing surgical procedures involving craniotomy and burr-hole biopsy. The study evaluation form verified that the users found the product safe and effective to use for rigid head fixation, the intended use, so hence is substantially equivalent to the predicate device.

Non-clinical tests being submitted include verification that the mechanical properties remain the same after cleaning, packaging (including transport and shelf life) and sterilization and a full set of mechanical tests verifying that the device meets the requirements and specifications derived during the Brainlab product design and development process. The results of these tests showed that the device is safe and effective to use for rigid head fixation so hence is substantially equivalent to the predicate device.

Testing of the Sterile Radiolucent Skull Pins compatibility with the specified head holders has been verified, particularly considering the orientation and application of forces to the patient's head. The conclusion of the testing was that for the head holder units listed on the instruction leaflet the product is safe and effective to use for rigid head fixation so hence is substantially equivalent to the predicate device.

In conclusion all verification and validation tests have been successfully completed to the pre-approved test protocols and have met the predefined acceptance criteria. We believe the information provided proves substantial equivalence with the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 26,2013

Brainlab AG
c/o Alexander Schwiersch
Kapellenstrasse 12
85622 Feldkirchen
Germany

Re: K122225
Trade/Device Name: Sterile Radiolucent Skull Pins
Regulation Number: 21 CFR 882.4460
Regulation Name: Neurosurgical Head Holder (Skull Clamp)
Regulatory Class: Class II
Product Code: HBL
Dated: April 22, 2013
Received: April 26, 2013

Dear Mr. Schwiersch:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to: http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to: http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address: http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joyce M. Whang -S

for Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122225

Device Name: Sterile Radiolucent Skull Pins

Indications For Use:

Sterile Radiolucent Skull Pins are designed for the fixation of a compatible head-holder unit to the patient's skull. This allows the fixation of the head and neck during craniotomy and subsequent neurosurgical procedures. These pins reduce the incidence of artifacts in images acquired intra-operatively using CT, MR (Conditional) or fluoroscopy.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ______ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Joyce M. Whang -S

(Division Sign Off)
Division of Neurological and Physical Medicine Devices (DNPMD)

510(k) Number K122225